





March 1, 2005

WRITER'S DIRECT NUMBER: (202) 772-8641 INTERNET ADDRESS: HCARLSON@SKGF.COM

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Hand Carry to Examiner Sharon L. Turner Art Unit 1647

Re:

U.S. Utility Patent Application

Application No. 10/791,905; Filed: March 4, 2004

For: Human G-Protein Chemokine Receptor (CCR5) HDGNR10

Inventors:

LI et al.

Our Ref:

1488.115000P/EKS/HCC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Second Supplemental Information Disclosure Statement;
- 2. PTO Form 1449 citing 84 documents;
- 3. A copy of 75 cited documents (AM21-AO21 and AR40-AT63); and
- 4. One return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents March 1, 2005 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Caly h. hougeworth 447,756 For Helene C. Carlson

Agent for Applicants Registration No. 47,473

EKS/HCC/eaf Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Confirmation No.: 3954

Li et al.

Art Unit: 1647

Appl. No.: 10/791,905

Filed: March 4, 2004

Examiner: Sharon L. Turner

Atty. Docket: 1488.115000P/EKS/HCC

For: Human G-Protein Chemokine Receptor (CCR5) HDGNR10

Second Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed on January 14, 2005, in connection with the above-captioned application.

The Examiner's attention is directed to the following co-pending application:

U.S. Application No. 10/994,679 (our Docket No. 1488.115000Q), inventors Roschke et al., filed November 23, 2004, not yet published (Document AR 64), which is directed to related technical subject matter. Pursuant to 37 C.F.R. § 1.183, a copy of this U.S. Patent Application is not provided (see also O.G. October 19, 2004). The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The

Examiner is respectfully requested to consider the cited application and the art cited

therein during examination.

Where the publication date of a listed document does not provide a month of

publication, the year of publication of the listed document is sufficiently earlier than the

effective U.S. filing date and any foreign priority date so that the month of publication is

not in issue. Applicants have listed publication dates on the attached PTO-1449 based on

information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on

the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention

over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the

teachings purportedly offered.

This statement should not be construed as a representation that a search has been

made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on

the material submitted herewith.

Applicants have checked the appropriate boxes below.

1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this

Information Disclosure Statement was cited in a communication from a foreign

patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

- 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.
 - a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

Li *et al.* Appl. No. 10/791,905 Our Docket No. 1488.115000P/EKS/HCC

	□ b.	Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item
		of information in this Information Disclosure Statement was cited
		in a communication from a foreign patent office in a counterpart
		foreign application and, to my knowledge after making reasonable
		inquiry, was known to any individual designated in 37 C.F.R.
		§ 1.56(c) more than three months prior to the filing of this
		Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
	☐ c.	Attached is our PTO-2038 Credit Card Payment Form in the
		amount of \$ in payment of the fee under 37 C.F.R. §
		1.17(p).
4 .	Filing under 3	37 C.F.R. § 1.97(d) This Information Disclosure Statement is being
	filed more tha	an three months after the U.S. filing date and after the mailing date
	of a Final Rej	ection or Notice of Allowance, but before payment of the Issue Fee.
	Enclosed fine	d our PTO-2038 Credit Card Payment Form in the amount of
	\$ i	n payment of the fee under 37 C.F.R. § 1.17(p); in addition:
	□ a.	Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each
		item of information contained in this Information Disclosure
		Statement was cited in a communication from a foreign patent
		office in a counterpart foreign application not more than three
		months prior to the filing of this Information Disclosure
		Statement. 37 C.F.R. § 1.97(e)(1).

b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2). 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38. 6. A concise explanation of the relevance of the non-English language document(s) appears below in accordance with 37 C.F.R. § 1.98(a)(3). □ 7. Copies of documents AM21-AO21 and AR40-AT63 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications, documents AC4-AJ4, cited on the attached Form PTO-1449 are submitted. 8. Copies of the documents were cited by or submitted to the Office in an IDS that

complies with 37 C.F.R. § 1.98(a)-(c) in Application No._____, filed

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Our Docket No. 1488.115000P/EKS/HCC

	, which is relied upon for an earlier filing date under 35 U.S.C.
	§ 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).
9 .	It is expected that the examiner will review the prosecution and cited art in the
	parent application noin accordance with MPEP
	2001.06(b), and indicate in the next communication from the office that the art
	cited in the earlier prosecution history has been reviewed in connection with the
	present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Graby L. Lougzworth

Helene C. Carlson

Agent for Applicants

Agent for Applicants Registration No. 47,473

Date: March 1, 2005

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

ATTY. DOCKET NO. APPLICATION NO. 1488.115000P/EKS/HCC 10/791,905 APPLICANT(S) Li et al. SECOND SUPPLEMENTAL ART UNIT

FORM PTO-1449

Page 1 of 25

FILING DATE INFORMATION DISCLOSURE STATEMENT 1647 March 4, 2004 U.S. PATENT DOCUMENTS **EXAMINER** DATE NAME CLASS SUB-CLASS **FILING DATE** INITIAL DOCUMENT NUMBER AA AB 06/13/1997 AC4 6.107.019 08/22/2000 Allaway et al. 04/02/1997 02/05/2002 Allaway et al. AD4 6,344,545 AE4 6,448,375 09/10/2002 Samson et al. 04/09/1997 07/11/1997 AF4 6.528.625 03/04/2003 Wu et al. 08/24/2001 6,692,938 02/17/2004 Samson et al. AG4 12/20/1996 AH4 6,797,811 09/28/2004 Gray et al. 10/05/2004 Samson et al. 08/24/2001 Al4 6,800,447 11/29/2000 20010000241 04/12/2001 Li et al. AJ4 ΑK **FOREIGN PATENT DOCUMENTS EXAMINER** DATE COUNTRY CLASS SUB-CLASS TRANSLATION INITIAL DOCUMENT NUMBER Yes AL No Yes WIPO 01/22/1998 AM21 WO 98/02151 No Yes 03/19/1998 **WIPO** AN21 WO 98/11218 No Yes **WIPO** 08/16/2001 WO 01/058915 A3 AO21 No Yes AP No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Baba, M., et al., "A small-molecule, nonpeptide CCR5 antagonist with highly potent and selective anti-AR 40 HIV activity," Proc. Natl. Acad. Sci. U.S.A. 96:5698-5703, National Academy of Sciences (May 1999) BD Pharmingen™ Technical Data Sheet, "R-Phycoerythrin (R-PE)-Conjugated Mouse Anti-human AS 40 Monoclonal Antibody," Revision 002, BD Biosciences Pharmingen (August 2004) Björndal, A., et al., "Coreceptor usage of primary human immunodeficiency virus type 1 isolates varies according to biological phenotype," J. Virol. 71(10):7478-7487, American Society for Microbiology <u>40</u> ΑT (1997)DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

EXAMINER

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ATIY. DOCKET NO. 1488.115000P/EKS/HCC APPLICATION NO. 10/791,905

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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Blanpain, C., et al., "Multiple charged and aromatic residues in CCR5 amino-terminal domain a involved in high affinity binding of both chemokines and HIV-1 Env protein," J. Biol. Chem. 274(49):34719-34727, American Society for Biochemistry and Molecular Biology (December 1					
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SECOND SUPPLEMENTAL, INFORMATION DISCLOSURE STATEMENT

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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March 4, 2004

ATTY. DOCKET NO. 1488.115000P/EKS/HCC APPLICATION NO. 10/791,905

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March 4, 2004

Li et al.

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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	AS	Farzan, M., et al., "A Tyrosine-rich region in the N terminus of CCR5 is important for human immunodeficiency virus type 1 entry and mediates an association between gp120 and CCR5," J 72(2):1160-1164, American Society for Microbiology (February 1998) Fleuridor, R., et al., "CD1d-restricted natural killer T cells are potent targets for						
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 1488.115000P/EKS/HCC 10/791,905 APPLICANT(S) Li et al. FILING DATE ART UNIT March 4, 2004 1647

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ATTY. DOCKET NO.	Application No.	
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SECOND SUPPLEMENTAL, INFORMATION DISCLOSURE STATEMENT

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Li *et al.*FILING DATE ART UNIT

March 4, 2004 1647

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FORM	PTO-1449

SECOND SUPPLEMENTAL

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 1488.115000P/EKS/HCC

APPLICATION No. 10/791,905

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APPLICANT(S)

Li et al.

FILING DATE March 4, 2004 ART UNIT 1647

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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	АТ	49	down-modulate s	urface CCR	eactive antibodies in s 5 in vivo and neutrali e American Associatio	ze the infectivity	of R5 strains of	of HIV-1 in vitro," J.
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	AS	<u>50</u>	Lyerly, H.K., et a. anti-HIV ADCC,"	I., "Anti-gp 120 AIDS Res. Hu	antibodies from HIV se um. Retroviruses 3:409-4	ropositive indi 122, Mary Ann	viduals mediate Liebert, Inc. (19	broadly reactive 87)
	АТ	<u>50</u>	Martin, J.C. and infection," <i>J. Acq</i>	Bandrés, J.C. uir. Immune D	, "Cells of the monocyte efic. Syndr. 22(5):413-4	-macrophage 40, Lippincott \	ineage and path Williams and Wil	logenesis of HIV-1 kins, Inc. (1999)
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	AS	53	Perera, L.P., et J. Immunol. 162	<i>al.,</i> "IL-15 indo::2606-2612, T	uces the expression o	of chemokines and ation of Immunolog	their receptors in gists (1999)	ո T lymphocytes,"
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	AS	<u>55</u>	Roederer, M., et Invest. 99(7):155	<i>al.</i> , "HIV doe: 5-1564, The	s not replicate in nai American Society fo	ive CD4 T cells so or Clinical Investig	timulated with CD pation, Inc. (1997)	3/CD28," <i>J. Clin.</i>
	AT	<u>55</u>	Rottman, J.B., e targets of HIV-1 Pathology (1997)	I infection,"	ar localization of th Amer. J. Path. 15	ne chemokine re 51(5):1341-1351,	ceptor CCR5: cc American Socie	orrelation to cellular ety for Investigative
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	AS	<u>56</u>	Samson, M., et specificity," J. E Biology, Inc. (19	Biol. Chem. 272	nd extracellular loop 2(40):24934-24941, /	of CCR5 is the m American Society	ajor determinant of for Biochemistry	of ligand and Molecular
	AT	<u>56</u>	Samson, M., et CCR-5 chemok	<i>al.</i> , "Resistandine receptor ge	ce to HIV-1 infection ene," <i>Nature 382(22)</i>	in Caucasian indi :722-725, Nature	viduals bearing m Publishing Group	outant alleles of the (August 1996)
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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	AT	<u>58</u>	cells that are re	efractory to CC	ional deletion of the CC R5-dependent HIV-1 i ational Academy of Sc	nfection and cell	fusion," Proc. Na	unization produces tl. Acad. Sci.
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	AR	<u>60</u>	Trkola, A., et al., '1 isolates that use Society for Microb	e either the C0	sed neutralization as CR5 or the CXCR4 c nber 1999)	say for primary coreceptor," J. V	human immunod <i>irol. 73(11):</i> 8966-	eficiency virus type 8974, American
	AS	<u>60</u>	Trkola, A., et al., CCR5 monoclona (January 2001)	"Potent, broad al antibody PR	-spectrum inhibition O 140," <i>J. Virol.</i> 75(2	of human immu 2):579-588, Ame	inodeficiency viru erican Society for	s type 1 by the Microbiology
	АТ	<u>60</u>	Tuttle, D.L., et al. macrophage susc 4969, American S	ceptibility to in	of CCR5 increases of fection by human in robiology (1998)	during monocyte	e differentiation a y virus type 1," J	nd directly mediates . Virol. 72(6): 4962-
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	AS	<u>61</u>	syncytium-ind	ucing and syncy	ial coreceptor expre tium-inducing HIV- on, Inc. (October 20	1," J. Clin. Inves	independent evolu t. 106(8):1039-1052	tion of non- 2, The American
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